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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/662,784	09/15/2000	Malcolm L. Gefter	IMI-044DV3CN	3152

959 7590 12/13/2006

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EXAMINER	
EMCH, GREGORY S	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

TE

Office Action Summary	Application No.	Applicant(s)	
	09/662,784	GEFTER ET AL.	
	Examiner	Art Unit	
	Gregory S. Emch	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2006 and 16 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *95,96,101-104 and 111* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *95,96,101-104 and 111* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *95,96,101-104 and 111* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Seq. alignment A*.

DETAILED ACTION

Response to Amendment

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Gregory S. Emch, Art Unit 1649.

Claims 95, 96 and 101 have been amended and new claim 111 has been added as requested in the amendment filed on 16 November 2006. Following the amendment, claims 95, 96, 101-104 and 111 are pending in the instant application.

Claims 95, 96, 101-104 and 111 are under examination in the instant office action.

The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicants' response and withdrawn.

Election/Restriction

Applicants' election with traverse of Group K, Fel 31-2, residues 14-39 of SEQ ID NO: 6 in the reply filed 16 November 2006 is acknowledged. The traversal is on the ground(s) that the groups do not differ from each other but are similar in structure function and search and would not place undue burden upon the Examiner. Further, Applicants argue that the epitope portions share structural and functional features in

that they are related to SEQ ID NO: 6, that some epitopes share significant portions and that all can be used to reduce allergic responses to cat antigen. This is not found persuasive because the different sequence identifiers and portions define different structural constraints, in particular with respect to epitopes and therefore are capable of different effects and usage. Because the searches are different, each from the other, the searches are not co-extensive, and a search for a single member would not reveal all pertinent art to the other members. Further, the search for any one epitope portion does not necessarily constitute a search for any other and in addition different epitopes are recognized in the art as having distinct properties in stimulating immunity and immune responses. Rejoinder will only be considered upon the indication of allowable subject matter that is suitably linking.

The requirement is still deemed proper and is therefore made FINAL.

Double Patenting

The obviousness-type double patenting rejections of claims 95, 96 and 101-104 as being unpatentable over claims 1-33 of U.S. Patent No. 6.019,972 and over claims 1-24 of U.S. Patent No. 5,547,669 is maintained for reasons of record and as set forth infra. Furthermore, claim 111 is also subject to the instant obviousness-type double patenting rejections.

In the reply filed 06 March 2006, Applicants assert that upon indication of allowable claims in the pending application, Applicants will file a terminal disclaimer, if appropriate. However, until such a time occurs, the rejection is maintained.

Claim Rejections - 35 USC § 102

The rejection of claims 95, 96 and 101-104 under 35 U.S.C. 102(b) as being anticipated by Leiterman et al., J. Allergy Clin. Immunol., 74:147-53, 1984, as evidenced by UniProt_03 alignment with accession No. P30440, April 1, 1993 as further evidenced by Harlow & Lane Cold Spring Harbor Labs, 1988, pp. 427 is maintained for reasons of record and as set forth *infra*. Furthermore, claim 111 is also subject to the instant rejection under 35 U.S.C. 102(b).

In the reply filed 06 March 2006, Applicants assert that the claims are drawn to isolated polypeptides having specified amino acid sequences and compositions comprising such polypeptides and that the specification defines the term "isolated" as referring to the TRFP protein or peptides free of all other cat polypeptides or contaminants. Applicants assert that this is in contrast to Leiterman et al. who describe partial purification of cat allergen 1. Thus, Applicants assert that since the protein components taught by Leiterman et al. are not free of all other house dust mite proteins, then the claims are not anticipated. Applicants also cite case law that allegedly supports the position that that purity can be a basis for patentability. Applicants also assert that Leiterman et al. fail to teach or suggest the particular epitope-containing peptides encompassed by the claims.

Applicants' arguments have been fully considered and are not found persuasive.

The fact that Applicants define the term "isolated" as free of all other contaminants is irrelevant. Applicants are reminded that although the claims are

interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In addition, although *In re Bergstrom* concerns patentability of pure PGE_2 and PGE_3 as compared to the compounds in impure form, the fact pattern is different from that of the instant case. In the instant case, Applicants assert that the claimed peptides are novel in view of the same peptides that are partially purified. In *In re Bergstrom*, PGE_2 and PGE_3 were considered novel over prior art that taught a crude glandular extract that possessed the same function (e.g., smooth muscle stimulation and depression of blood pressure) as the purified amino acid molecules. Here, the prior art did not explicitly spell out the presence of the two substances PGE_2 and PGE_3. The court stated:

> "Indeed, the board concedes that '[n]either the examiner nor we have held that the [Bergstrom] publication explicitly spells out the presence of these two substances,' making it apparent that the claimed pure compounds were not 'described in a printed publication in * * * a foreign country' more than one year prior to the filing date of appellants' present application. As far as the record shows, then the claimed subject matter is described and made known to the public for the first time only in the present application." *In re Bergstrom and Sjovall*, 166 USPQ 256, 261 (C.C.P.A. 1970)

Similarly, in *Ex parte Stern*, 13 USPQ2d 1379 (Bd. Pat. App. & Int. 1987), the purified IL-2 was considered novel because the appellant purified IL-2 to homogeneity and "defined [it] in terms of heretofore unascertained properties which include specific activity and amino acid composition data." *Id.* at 1380.

Thus, the fact patterns in these cases are different from that of the instant case, because here, the prior art has indeed described the claimed compounds (structurally

and functionally) in a printed publication more than one year prior to the filing date of the instant application. Leiterman et al. explicitly teaches "Cat allergen 1" which consists of amino acids 3-111 of Applicants' SEQ ID NO: 6 (see attached sequence alignment A) and it's biochemical, antigenic and allergenic properties. Thus, the public had knowledge of and possession of the claimed peptides prior to Applicants' priority date.

Furthermore, the fact pattern in *Merck & Co., Inc. v. Chase Chemical Co. et al.*, 155 USPQ 139 (D.N.J. 1967) is actually in opposition to Applicants' assertions. Applicants seem to refer to the plaintiff's patents, which were issued based on isolation of vitamin B-12 from crude liver abstracts. Here, vitamin B-12 was previously unknown as part of the extracts (again contrary to the instant fact pattern). In this case, it was held that the defendants infringed on the Merck's patents by "further isolating" vitamin B-12. Thus, the holding in this case is in direct opposition with Applicants' arguments.

Additionally, regarding Applicants' assertions that Leiterman et al. fail to teach or suggest the particular epitope-containing peptides encompassed by the claims, the claims use the open language "comprising," which does not exclude additional unrecited elements or method steps (see MPEP 2111.03). For example, claim 95 reads, "A therapeutic composition, comprising an isolated polypeptide selected from the group consisting of: (a) an isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 6; (b) an isolated polypeptide comprising at least a portion of the sequence of (a) which comprises at least one epitope of the polypeptide of (a), wherein the portion is selected from the group consisting of: (the claimed Fel peptides); or an epitope-containing portion thereof..." Thus, the instant claims read on peptides

comprising the claimed epitopes with additional amino acids, such as the protein of the Leiterman et al. reference. The Leiterman protein anticipates the current claims since it consists of amino acids 3-111 of Applicants' SEQ ID NO: 6 (see attached sequence alignment A), which encompasses the majority (all but Fel16) of the epitope-containing peptides recited in said claims.

Conclusion

No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached on Monday through Friday from 9AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gregory S. Emch, Ph.D.
Patent Examiner
Art Unit 1649
08 December 2006

ELIZABETH KEMMERER
PRIMARY EXAMINER

SEQ ID NO: 6
FEL2_FELCA
ID FEL2_FELCA STANDARD; PRT; 109 AA.
AC P30440;
DT 01-APR-1993 (Rel. 25, Created)
DT 01-APR-1993 (Rel. 25, Last sequence update)
DT 15-MAR-2004 (Rel. 43, Last annotation update)
DE Major allergen I polypeptide chain 2 precursor (Allergen Fel d 1-B)
DE (Fel d I-B) (Allergen Cat-1) (AG4) (FdI).
GN CH2.
OS Felis silvestris catus (Cat).
OC Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi;
OC Mammalia; Eutheria; Carnivora; Fissipedia; Felidae; Felis.
OX NCBI_TaxID=9685;
RN [1]
RP SEQUENCE FROM N.A., AND SEQUENCE OF 18-100.
RX MEDLINE=92052157; PubMed=1946388;
RA Morgenstern J.P., Griffith I.J., Brauer A.W., Rogers B.L.,
RA Bond J.F., Chapman M.D., Kuo M.-C.;
RT "Amino acid sequence of Fel dI, the major allergen of the domestic
RT cat: protein sequence analysis and cDNA cloning.";
RL Proc. Natl. Acad. Sci. U.S.A. 88:9690-9694(1991).
RN [2]
RP SEQUENCE FROM N.A., ALTERNATIVE SPLICING, AND VARIANTS.
RC TISSUE=Liver;
RX MEDLINE=92241678; PubMed=1572548;
RA Griffith I.J., Craig S., Pollock J., Yu X.-B., Morgenstern J.P.,
RA Rogers B.L.;
RT "Expression and genomic structure of the genes encoding FdI, the
RT major allergen from the domestic cat.";
RL Gene 113:263-268(1992).
RN [3]
RP SEQUENCE OF 18-37, AND CHARACTERIZATION.
RX MEDLINE=91287714; PubMed=1712068;
RA Duffort O.A., Carreira J., Nitti G., Polo F., Lombardero M.;
RT "Studies on the biochemical structure of the major cat allergen Felis
RT domesticus I.";
RL Mol. Immunol. 28:301-309(1991).
RN [4]
RP CHARACTERIZATION.
RX MEDLINE=84265679; PubMed=6747135;
RA Leiterman K., Ohman J.L. Jr.;
RT "Cat allergen 1: Biochemical, antigenic, and allergenic properties.";
RL J. Allergy Clin. Immunol. 74:147-153(1984).
CC -!- SUBUNIT: Heterotetramer composed of two non-covalently linked
CC disulfide-linked heterodimer of chains 1 and 2.
CC -!- ALTERNATIVE PRODUCTS:
CC Event=Alternative splicing; Named isoforms=3;
CC Comment=Experimental confirmation may be lacking for some
CC isoforms;
CC Name=1; Synonyms=CH2L;
CC IsoId=P30440-1; Sequence=Displayed;
CC Name=2; Synonyms=CH2S;
CC IsoId=P30440-2; Sequence=VSP_004249;
CC Name=3; Synonyms=CH2ST, Truncated;
CC IsoId=P30440-3; Sequence=VSP_004248;
CC -!- TISSUE SPECIFICITY: The long form is preferentially expressed in
CC the salivary gland, while the short form is preferentially
CC expressed in the skin.
CC -!- ALLERGEN: Causes an allergic reaction in human. Major allergen
CC produced by the domestic cat.
CC ---

```
CC   or send an email to license@isb-sib.ch).
CC   ---------------------------------------------------------------------
DR   EMBL; M77341; AAC41616.1; -.
DR   EMBL; X62478; CAA44345.1; -.
DR   PIR; B53283; B53283.
DR   PIR; C56413; C56413.
DR   PIR; JC1127; JC1127.
DR   InterPro; IPR006038; Uteroglobin_supf.
KW   Allergen; Glycoprotein; Signal; Polymorphism; Alternative splicing.
FT   SIGNAL        1     17
FT   CHAIN        18    109       MAJOR ALLERGEN I POLYPEPTIDE CHAIN 2.
FT   CARBOHYD     50     50       N-LINKED (GLCNAC. . .).
FT   VARSPLIC     82    109       TTISSSKDCMGEAVQNTVEDLKLNTLGR -> PSTNIAWVK
FT                                 QFRTP (in isoform 3).
FT                                 /FTId=VSP_004248.
FT   VARSPLIC     82     89       TTISSSKD -> IAINEY (in isoform 2).
FT                                 /FTId=VSP_004249.
FT   VARIANT      72     72       I -> L (IN CH2LV).
FT   VARIANT      72     72       I -> V (IN CH2SV).
FT   VARIANT      74     75       RV -> KF (IN CH2SV).
FT   VARIANT      91     91       M -> T (IN CH2LV).
FT   VARIANT      96     96       Q -> E (IN CH2SV).
FT   VARIANT     105    105       N -> K (IN CH2SV).
FT   CONFLICT     24     24       C -> F (IN REF. 3).
FT   CONFLICT     32     32       F -> T (IN REF. 3).
SQ   SEQUENCE   109 AA;  11854 MW;  857FB9CD76036CB9 CRC64;

  Query Match             98.0%;  Score 541;  DB 1;  Length 109;
  Best Local Similarity   100.0%;  Pred. No. 1.1e-49;
  Matches  109;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          3 MRGALLVLALLVTQALGVKMAETCPIFYDVFFAVANGNELLLDLSLTKVNATEPERTAMK 62
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MRGALLVLALLVTQALGVKMAETCPIFYDVFFAVANGNELLLDLSLTKVNATEPERTAMK 60

Qy         63 KIQDCYVENGLISRVLDGLVMTTISSSKDCMGEAVQNTVEDLKLNTLGR 111
              |||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 KIQDCYVENGLISRVLDGLVMTTISSSKDCMGEAVQNTVEDLKLNTLGR 109
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